A PROSPECTIVE RANDOMIZED CONTROL STUDY TO COMPARE THE EFFIACACY OF CONCENTRATED GROWTH FACTOR FOLLOWING SURGICAL REMOVAL OF IMPACTED MANDIBULAR 3rd MOLAR

A Dissertation submitted

in partial fulfilment of the requirements

For the degree of

MASTER OF DENTAL SURGERY

BRANCH –III

ORAL AND MAXILLOFACIAL SURGERY

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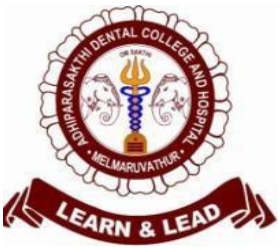

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY

CERTIFICATE

This is to certify that **DR.R.MURALIDHARAN**, Post Graduate student (2015-2018) in the Department of Oral and maxillofacial surgery, Adhiparasakthi Dental college and Hospital, Melmaruvathur-603319, has done this dissertation titled **"A PROSPECTIVE RANDOMIZED CONTROL STUDY TO COMPARE THE EFFIACACY OF CONCENTRATED GROWTH FACTOR FOLLOWING SURGICAL REMOVAL OF IMPACTED MANDIBULAR 3rd MOLAR"** under our direct guidance and supervision in partial fulfilment of the regulations laid down by the Tamilnadu Dr. M.G.R medical university, Chennai-600032 for MDS; (Branch –III) Oral and maxillofacial surgery degree examination.

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DECLARATION

Title of the Dissertation	A PROSPECTIVE RANDOMIZED CONTROL STUDY TO COMPARE THE EFFIACACY OF CONCENTRATED GROWTH FACTOR FOLLOWING SURGICAL REMOVAL OF IMPACTED MANDIBULAR 3rd MOLAR
Place of the Study	Adhiparasakthi Dental College & Hospital, Melmaruvathur-603319.
Duration of the Course	3 Years
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ABSTRACT

BACK GROUND

Tissue regeneration is the biggest goal of rehabilitation therapies today, for which many products and techniques have been used (Tissucol, PRP, PDGF, PRF etc). Though none of the systems proved to be successful for an appropriate bio stimulation, as these techniques do not exploit the regenerative potential of the components of the whole blood. The concentrated growth factor technique envisages the use of all the separated blood phases which can be disposed individually in order to obtain the bio stimulation of related cells or tissues.

The Concentrated Growth Factor as a regenerative tool for accelerated wound healing was developed by Sacco in 2006, taking advantage of presence of adult stem cells and growth factors when whole blood is processed in a specific cycle. This presentation is about the role of CGF in early accelerated tissue healing in minor oral surgical procedures of a health individual.

Extraction of an impacted mandibular third molar is a common surgical procedure, although it still leads to several postoperative symptoms and complications. The study assessed the efficacy of concentrated growth factors in the healing process by checking the difference of tissue cytokines and other healing factors produced by the mucosa after extraction between sites treated with CGF and control sites and, at the same time, by evaluating the clinical efficacy of CGF in terms of reduced pain and facial swelling. This study was a split-mouth study, in which the patient becomes his/her own control, to eliminate any individual response differences toward CGF treatment. The parameters regarding inflammation and subsequent wound healing were all significantly higher at CGF sites than at control sites. The increase at PRGF sites of the two proinflammatory cytokines evaluated, interleukin (IL)-1β and IL-6, is accompanied by the increase of two anti-inflammatory cytokines, IL-10 and transforming growth factor-β. Furthermore, IL-1β and IL-6 induce fibroblast and keratinocyte proliferation, important events in wound healing. Postoperative pain and the swelling, measured at all experimental times, were reduced in the presence of CGF.

Aim and Objectives:

The purpose of this study is to evaluate and compare utility and efficacy of concentrated growth factor on soft tissue healing and bone healing following surgical removal of a mandibular impacted 3rd molar with the control group.

Materials and Methods:

Sampling procedure	**Random selection of population**
No. of Groups	Two Control group (Group 1) & Experimental group (Group 2)
Sample size	15 + 15=30

Patient selection:

Patients were selected by means of volunteers' recruitment process. Patients interested in the surgical removal of mandibular 3rd molars were included in the study. Symptomatic and asymptomatic patients were selected and inform consent form signed.

This prospective randomized control blind study was carried out to evaluate and compare utility and efficacy of concentrated growth factor on soft tissue healing and bone healing following surgical removal of mandibular impacted 3rd molar in 15 patients by fulfilling the inclusion and indication criteria. All patients had moderately difficult impacted lower third molar according to modified Pederson's index.

Conclusion:

The results of this study indicates that CGF is significantly better in regeneration of bone around the surgical removal of mandibular molar when comparing with non-CGF groups. Although, CGF showed improvement in both soft tissue healing and bone formation, there is much differences in bone level changes on mesial and distal side of the surgical removal of impacted teeth between two groups. CGF did attribute to be a much simpler and a better platelet concentrate, in promoting osseous regeneration. CGF also aided in increasing the density of bone around the surgical removal of impacted 3rd molar teeth from baseline to a much higher level. This attribute could be used in cases where bone mineralization is compromised. But the exact action of CGF on bone mineralization needs to be studied further.

Key words:

Impacted 3rd molar, Concentrated Growth factor.

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INTRODUCTION

Surgical extraction of impacted mandibular third molar is one of the most common minor surgical procedure performed by the Oral and Maxillofacial Surgeons [1]. As with any surgical removal of impacted lower third molar is always associated with postoperative complications. In the orofacial area has physical, psychological and esthetic ramifications of considerable degree. It has been reported that there is a threefold decrease of adverse effects on quality of life [2] due to postoperative complications such as pain, swelling and trismus.

The surgical removal of third molar (wisdom teeth) generally produces pain, trismus and facial swelling in the postoperative period [3]. The many factors that contribute toward these conditions are complex, but originate in an inflammatory process initiated by surgical trauma [4]. The postoperative effect of wisdom tooth surgery on quality of life is reported to be threefold greater in patients who experience pain, swelling and trismus (either alone or in combination) in comparison to asymptomatic patients [5].

Many clinicians have therefore stressed the need for better pain, swelling and trismus control in patients who undergo third molar surgery [6]. There have been few attempts to study patients expectations regarding outcomes, although patients perceptions of recovery following third molar surgery have been reported.[5,7-9]

Growth factors:

Growth factors are proteins which regulate the complex processes of wound healing. Growth factors play a main role in cell migration, cell proliferation and angiogenesis in tissue regeneration phase. These growth factors are mainly located in blood plasma and platelets. Platelet concentrate such as platelet rich plasma (PRP) has been used to accelerate soft tissue healing for a long time. Platelet rich fibrin was introduced by Choukroun for the first time. The effect of Platelet rich plasma is controversial with regards to hard tissue regeneration. Platelet rich plasma needs complex protocols to prepare and chemical additives are required. But concentrated growth factors (CGF) overcome these disadvantages of Platelet rich plasma. The preparation of Concentrated growth factor is simple. Compared to Platelet rich fibrin, Concentrated growth factor is attained by single a centrifugation using special centrifuge.

Concentrated Growth Factors (CGF) has been suggested to enhance the healing of bone grafts and enhance the integration of bone in the extraction socket. Concentrated growth factor was first developed by Sacco in 2006. It can be used as a barrier membrane to accelerate soft tissue healing. Concentrated growth factor does not require any chemical or anticoagulants so it is free from viral transmission diseases. Concentrated growth factor is 100% autologous. Unlike Platelet rich plasma, Concentrated growth factors is well known to accelerate healing. Concentrated growth factors is also an alternative to bone substitutes in sinus augmentation. One step protocol is needed to obtain

Concentrated growth factors from the blood sample, unlike platelet rich plasma bone formation.

Surgeons use Concentrated growth factors as a barrier membrane to accelerate the soft tissue healing or can be mixed with bone graft to accelerate new bone formation.Whether the use of CGF to enhance Osseointegration, thus leading to better success on surgical removal of impacted tooth is yet to be studied.

AIMS AND OBJECTIVE

The purpose of this study is to evaluate and compare utility and efficacy of concentrated growth factor on soft tissue healing and bone healing following surgical removal of a mandibular impacted 3rd molar with the control group.

REVIEW OF LITERATURE

R E Marx et al (1998)[14], found that the Platelet-rich plasma is an autologous source of platelet-derived growth factor and transforming growth factor beta that is obtained by sequestering and concentrating platelets by gradient density centrifugation. This technique produced a concentration of human platelets of 338% and identified platelet-derived growth factor and transforming growth factor beta within them. Monoclonal antibody assessment of cancellous cellular marrow grafts demonstrated cells that were capable of responding to the growth factors by bearing cell membrane receptors additional amount of growth factors obtained by adding PRP to grafts evidenced a radiographic maturation rate 1.62 to 2.16 times that of grafts without platelet- rich plasma.

P Edward Anitua MD, DDS et al (1999),[11] found that the use of platelet rich growth factor provides conditions for obtaining more rapid and effective bone regeneration. Platelet rich growth factor gel which is a coagulated mass is easy to manipulate, but it must be applied without delay to preserve growth factor activity. In addition to these growth factors, other proteins carried platelets may act with other cytokines released from other cellular sources, modulating hemostasis. These results suggest that reinforcing growth factor concentration through the application of PRGF in the wound improves soft tissue repair and bone regeneration. No negative effect has been found and the epithelialisation has been complete and significantly better than in areas not treated with PRGF.

A.Dugrillonetal et al(2002)[18], concluded that platelets are rich in growth factors and may contribute to an accelerated tissue regeneration process. The therapeutic osteogenic effect of local platelet administration probably depends on the amount of growth factors delivered within. To improve platelet-derived factor preparations, the platelets have to be concentrated without loss of the granular growth factor load. An autologous procedure according to the Good Manufacture Practice (GMP) guidelines to prepare a high concentrate from platelet-rich plasma (cPRP) for clinical application in bone regeneration is necessary.

Michael Tischler DDS et al(2002)[16], concluded that the application of PRP offers the patient something that is safe from outside disease transmission or immunogenic reactions. PRP preparation can be easily obtained in dental office environment and can be used for various procedures being done. The growth factor enhancement is especially applicable for patients who are healing impaired such as elderly. Platelet rich plasma appears to enhance both hard tissue and soft tissue healing through concentrated platelets and growth factors such as platelet derived growth factor (PDGF) and Transforming growth factor β (TGF – β).

Kazuhiro et al(2003)[19], concluded that PRP has been thought, but not well demonstrated, to contain certain growth factors, such as PDGF and TGF β, at high concentrations. In general, it has not been demonstrated that these growth factors in PRP are involved in accelerating

regeneration of periodontal tissue damaged by periodontitis. This study for the first time shown the PRP containing these growth factors efficiently and effectively regulated the proliferation of periodontal related cells in culture.

G Weibrich et al(2004)[20], concluded that PRP seems to be able to activate the osseous regeneration processes under optimized conditions. The simulatory effect of PRP in vitro on the proliferation of osteoblasts seems to start in vivo in the second week, can be evaluated statistically significant from the third week, and still exists in the fourth week. The platelet concentration required for a positive PRP effect seems to span a small range of concentration. Advantageous biological effects seem to appear when PRP with a platelet concentration of approximately 1000000/µl is used. At lower concentration the effect is suboptimal while higher concentration might have a paradoxically inhibitory effect.

R L Eppley et al(2004)[12], found that the platelets can be sequestered and concentrated eight fold from whole blood without activating the platelets before desired. These platelets contain a host of growth factors, such as PDGF-BB, TGF-[beta]1, VEGF, and EGF, whose levels are increased when platelets are concentrated into platelet-rich plasma gel preparations. Platelet-rich plasma, and the associated fibrin clot, can potentially aid in wound repair and help to maintain hemostasis, or can be mixed with other tissues as an adjunct to their transplantation. However growth factor concentration varied from patient to patient.

Sufficient concentrates and release of these growth factors through autologous platelet gels may be capable of expediting wound healing.

Khoury et al (2006)[10], concluded that promising accelerated osseointegration results have been obtained with Platelet rich plasma at implant sites, which is regarded as a very interesting finding in maxillary areas, fracture sites type IV bone and in females with osteoporosis. Moreover soft tissue heals better with platelet rich plasma. The platelet gel is more frequently used in reconstructive and plastic facial surgery and provides greater patient comfort. It is probable that tissue engineering and genetic therapies modify implant and regenerating strategies if all ongoing studies confirm such results.

Hesham El-sharkawy et al(2007)[13], found that Growth factors were increased significantly in PRP compared to whole blood (WB) and platelet-poor plasma. Monocyte chemotactic protein-1 (MCP-1) was suppressed significantly by PRP, whereas regulated on activation, normal T-cell expressed and secreted RANTES was increased significantly in monocyte cultures. LXA(4) levels were significantly higher in PRP compared to WB. PRP stimulated monocyte chemotaxis in a dose-dependent fashion, whereas RANTES, in part, was responsible for PRP-mediated monocyte migration. Platelet rich plasma promotes regeneration of bone presumably through the action of CGF. However it is not clear how PRP affects the inflammatory response.

Dong-seoksohnet al[25] (2009)[25], found that growth factors play a major role to repair or generate damaged tissue. Most of growth factors are in blood plasma and platelet. So platelet concentrates contains sufficient growth factors such as platelet derived growth factors (PDGF), transforming growth factor-beta (TGF-β), Insulin-like growth factor (IGF-I), epidermal growth factor(EGF), vascular endothelial growth factor (VEGF), basic fibroblast growth factor (bFGF). PRP has widely been used in the dental field such as sinus augmentation, ridge augmentation, periodontal regeneration and soft tissue healing. However the effect of PRP is controversary. According to one systemic review on the effect of PRP, the beneficial effects of PRP in the treatment of periodontal defects is evident but evidence for beneficial effects of PRP in sinus elevation appeared to be weak.

Dr.Manimaran et al (2010)[17], found that the properties of Platelet rich plasma are based on the activation and release of multiple growth factors upon activation. They enhance and accelerate soft tissue healing and bone regeneration. Owing to the availability of these growth factors in high concentration of platelets, use of Platelet rich plasma offers distinct advantages over other media containing natural or recombinant factors. The action of these factors are very complex because individual action on same tissues vary depending upon local factors and interaction between one another. Most of the advantages regarding PRP are still in research.

Dr.Kiran NK et al(2011)[23], concluded that the affinity of osteoblasts to the PRF membrane appeared to be superior. PRF has many advantages over PRP. It eliminates the redundant process of adding anticoagulant as well as the need to neutralize it. The addition of bovine derived thrombin to promote conversion of fibrinogen to fibrin in PRP is also eliminated. The elimination of these steps considerably reduces biochemical handling of blood as well as risks associated with the use of bovine derived thrombin. Platelet rich fibrin has more advantages over platelet rich plasma and very favourable to the healing process due to slow polymerisation reaction.

Dr.Kedarnath et al (2011)Platelet-rich plasma (PRP) is an autologous Concentration of human platelets in a small volume of plasma. Because it is a concentration of platelets, it is also a concentration of the 7 fundamental protein growth factors proved to be actively secreted by platelets to initiate all wound healing. These growth factors include 3 isomers of platelet-derived growth factors (PDGFĮĮ, PDGFùù, and PDGFĮù), 2 of the numerous transforming growth factors-ù (TGFù1 and TGFù2), vascular endothelial growth factor, and epithelial growth factor. All these growth factors have been documented to exist in platelets. Because these concentrated platelets are suspended in a small volume of plasma, PRP is more than just a platelets concentrate; it also contains the 3 proteins in blood known to act as cell adhesion molecules for osteoconduction and as a matrix for bone, connective tissue, and epithelial migration . Platelet-rich plasma (PRP), the concentrate of platelets in plasma contains various Growth

factors that enhance osseous regeneration.Soft tissue healing differed significantly between PRP and NON-PRP sites.On radiographic evaluation significant differences were observed in the mean scores of radiographic density between PRP and NON-PRP sites on Photo Stimulating Phosphor (PSP) images and IOPA Radiographs.

BalaramNaik et al (2013)[22], conclude that PRF first described by Choukroun is a new second generation of platelet concentrate. Simplified processing technique without any complex handling makes it superior to PRP. PRF can be used to promote wound healing, bone regeneration, graft stabilization, wound sealing, and hemostasis. Because the fibrin matrix is better organized, it is able to more efficiently direct stem cell migration and the healing program. Release of growth factors from PRF through in vitro studies and good results from in vivo studies led to optimize the clinical application of PRF. It was shown that there are better results of PRF over PRP. Dohan proved a slower release of growth factors from PRF than PRP and observed better healing properties with PRF. It was observed and shown that the cells are able to migrate from fibrin scaffold, while some others demonstrated the PRF as a supportive matrix for bone morphogenetic protein as well.

TejeshYelamali et al(2015)[15], concluded that PRF is significantly better in promoting soft tissue healing and also faster regeneration of bone after third molar extraction, in comparison with PRP. Although, both PRF and PRP clinically showed very good soft tissue healing as

measured by healing index of Landry et al., further studies with larger sample size are needed to show much convincing effects of these biomaterials in terms of soft tissue healing. Moreover, PRF definitely showed to promote better osseous regeneration over PRP in terms of uniformity and density of regenerated bone which is statistically significant. Although, the present study was done with a four month follow-up and the osseous regeneration was only measured indirectly over computer PRP.aided software (Adobe Photoshop CS), PRF did attribute to be a much simpler and a better platelet concentrate, in promoting soft tissue healing and osseous regeneration over PRP.

Peter mansour et al (2015)[26], concluded that during normal wound healing, the fibrin matrix is important in haemostasis, however more crucial is its role in acting as the initial scaffold for the new extracellular matrix. It allows binding of cells and healing proteins to the scaffold, such as platelets, WBCs, fibroblasts and osteoblasts, endothelial cells, and smooth muscle cells. Fibrin has also been shown in animal models to be an important determinant of angiogenesis, as fibrin deposited in subcutaneous tissue induces angiogenesis. Furthermore, many studies have shown that wound healing is largely dictated by fibrin structure, in density, number of branch points, porosity and permeability. The fibrin physical structures are determined by many factors including clotting rate, Factor XIII concentration, thrombin, chloride ions, pH, etc.

MATERIALS AND METHOD

IRB Approval:

Before the start of the study, the methodology was presented to the IRB and approval was obtained.

IRB/IEC Reference No: **2015-MD-BrIII-GOK-06/APDCH**

Sampling procedure	Random selection of population
No. of Groups	Two Control group (Group 1) & Experimental group (Group 2)
Sample size	15 + 15=30

Patient selection:

Patients were selected by means of volunteers' recruitment process. Patients interested in the surgical removal of mandibular 3rd molars were included in the study. Symptomatic and asymptomatic patients were selected and inform consent form signed.

Inclusion criteria:

- Partially erupted or Completely Impacted mandibular 3rd molar (Symptamatic or Prophylatic)
- Patients between age of 20-40 years
- Absence of Active Acute infection.
- Patients willing to participate in the study by signing the inform consent form.
- Patients with healthy periodontal status

EXCLUSION CRITERIA

- Patient's allergic to LA or any medication
- Chronic Smokers and Alcoholic
- Patient's with Systemic disorder and Immunocomprised patient
- Pregnant and Lactating mother's
- Patients not willing to participate in the study

This prospective randomized control blind study was carried out to evaluate and compare utility and efficacy of concentrated growth factor on soft tissue healing and bone healing following surgical removal of mandibular impacted 3rd molar in 15 patients by fulfilling the inclusion and indication criteria. All patients had moderately difficult impacted lower third molar according to modified Pederson's index as follows,

Classification	**Value**
Spatial relationship:	
Mesio angular	1
Horizontal / Transverse	2
Vertical	3
Disto angular	4
Depth:	
Level A – High occlusal level	1
Level B – Medium occlusal level	2
Level C – Low occlusal	3

Ramus relationship / Space available:

Class 1 – Sufficient space	1
Class 2 – Reduce space	2
Class 3 – No space	3

Difficulty index

Very difficult	7-10
Moderately difficult	5-6
Slightly difficult	3-4

Study groups:

The selected patients were divided into 2 groups of 15 patients each.

30 patients with mandibular 3rd Impacted Mandibular 3rd Molar.

Group- A- 15patients as study group

Group- B- 15 patients as control group

Healthy patients with moderately difficult impacted mandibular third molars according to modified Pederson's difficulty index and patients who were willing to accept the inform consent and willing to participate in the study with its subsequent follow-ups were included in this study.

MATERIALS:

A) The kit will contain all necessary armamentarium for the blood collection and CGF specific vacuette tubes (Pre-sterlized)

BLOOD SAMPLING KIT:

1. 1.Antiseptic Swab
2. 2.Throwaway Tourniquet
3. Butterfly venflon
4. 4.Haemostaticband-aids
5. 5.Vacuette test tubes.

B) Centrifuge ((Medifuge MF200, Silfradent, Forli ,Italy) Blood phase separator for CGF)

PLATELET PLUG CONTAINER:

1. Surgical Tray
2. Dappen for fibrin separato
3. Griglia per separatore
4. Normal saline solution
5. Dappen Dish
6. Scissors with Round tip-Cutting instrument
7. Straight anatomic pliers
8. Pliers for membrane creation.
9. Compactor device
10. Surgical instrument tray.

C) Instruments specific to produce fibrin membrane and to insert the CGF in to the extraction site.

METHOD:

Impaction procedure:

Intraoral periapical radiogrpahs or Orthopantomogram were obtained to determine the type of impaction. Inferior alveolar, lingual and long buccal nerve anaethesia was achieved using a 2ml solution of 2% lignocaine hydrochloride and vasoconstrictor (1:80,000). Following a ward's incision a full thickness muco periosteal flap with releasing incision on the distobuccal aspect of the second molar was raised. After buccal and distal guttering the tooth was sectioned and gently elevated from the socket with subsequently flushed with normal saline and betadine. The flap was closed with 3-0 silk sutures in an interrupted fashion.

Blood Sample Centrifugation

1. The patient will be seated comfortably in the dental chair in semi supine position, In patient's fore arm tourniquet would be applied after Dabbing with antiseptic swab.
2. 9 mL of blood will be drawn from the anticubital region and collected in sterilisedVacuette tubes (Greiner Bio-One, GmbH, Kremsmunster, Austria) without anticoagulant solutions.
3. This tube will be immediately centrifuged in special machine (Medifuge MF200, Silfradent, Forli ,Italy) using a program with the following characteristics: 30'' acceleration, 2' 2,700 rpm, 4' 2,400 rpm, 4' 2,700 rpm, 3' 3,000 rpm, and 36" deceleration and stop.
4. At the end of the process there would be three blood fractions: (1)

the upper platelet poor plasma (PPP) layer; (2) the middle fibrin rich gel with aggregated platelets and concentrated growth factors (CGF); (3) the lower red blood cell (RBC) layer.

5. Middle fibrin rich layer along with the few mm of RBC layer would be cut and kept in the extraction socket and wound would be closed with 3-0 silk material. If required a plier would be used to create as membrane which will be placed in the extraction socket.

- **Criteria's to be evaluated for the study**
  - **Pain** (Visual Analogue Scale)
  - **Edema** (Comparison of pre-op & post-op measurements:

1. Distance between the cornerof the mouth to ear lobule;
2. Distance between the Ala of the nose to Angle of the mandible.

- **Wound dehiscence** (Cslinical examination for any discharge, Gaping, Discoloration over the mucosa)
- **Mouth opening** (Inter Incisal Distance in mm) (Maximum – 45mm)
- **Soft tissue healing-** Healing index by Landry et al
- **Dry socket**
- **Hard tissue healing-** IOPA (or) OPG

PAIN:

Pain was evaluated subjectively by Faces pain rating scale (VAS). This scale combines pictures and numbers to allow pain to be

rated by the patient. The faces range from smiling face to sad and crying face. A numerical rating has been assigned to these faces, ranging from 0 to 10 in ascending order, proportionate to increase of pain. The patient is asked to rate his or her pain using appropriate picture. (Figure 1)

SWELLING:

Facial measurements and maximum mouth opening were recorded pre operatively. Parameters recorded were swelling, pain, trismus and quality of life on 1st, 3rd, 5th and 7th day post operatively. Facial swelling was measured by a modification of tape measuring method described by Gabka and Matsumara. Three measurements were made between 5 reference points. (Figure 2,3, & 4)

1. Tragus of the ear
2. Soft tissue pogonion.
3. Lateral corner of the eye
4. Angle of the mandible
5. Outer corner of the mouth

WOUND DEHISCENCE

Blanching over the mucosa, Discharge, Gaping

Mouth opening

It was evaluated by measuring the distance between the mesial incisal corners of the upper and lower central incisors of Right / Left quadrant at maximum mouth opening with the help of divider. (Figure 5)

SOFT TISSUE HEALING (Landry et al Index**)**

A.VERY POOR:

- **Tissue colour :** > 50% Gingival red
- **Response to palpation**: Bleeding
- **Granulation tissue:** Present
- **Incision margin:** Not epithelialized, with loss of Epithelium beyond incision

B. POOR:

- **Tissue colour :** > 50% Gingival red
- **Response to palpation**: Bleeding
- **Granulation tissue:** Present
- **Incision margin :**Not epithelialized, with CT exposed

C. GOOD:

- **Tissue colour:** >25 and> 50% Gingival red
- **Response to palpation**: Bleeding
- **Granulation tissue:** Present
- **Incison margin:** Not epithelialized, with CT exposed

D. VERY GOOD

- **Tissue colour** : <25 of gingival red
- **Response to palpation:** No Bleeding
- **Granulation tissue:** None
- **Incision margin:** No Connective tissue exposed

E. EXCELLENT

- **Tissue colour:** All tissues pink
- **Response to palpation**: No Bleeding
- **Granulation tissue:** None
- **Incision margin:** No connective tissue exposed

BONE TISSUE HEALING:

- **Bone density:** Pre and Post OP (IOPA or OPG)
- **Duration:** 1 – 6 Months
- **No. of Radiographs:** 4 (Immediate, 1st, 3rd and 6th month)

Analysis of bone density:

The bone density was assessed by DIGORA software. Digora software has increased sensitivity in the detection of bone changes non-invasively. Four digitalized OPG are taken at pre-scheduled intervals. The images were compared at different intervals using DIGORA Software. The radiographic density differences between each interval were evaluated and analysed.

RESULTS

Method of Statistical Analysis:

The data collected were compiled using MS-Office Excel and was subjected to Statistical analyses were performed using IBM corp. Statistical Package for Social Sciences software for windows; version 22.0 (Armonk, NY). Data comparison was done by applying specific statistical tests to find out the statistical significance of the obtained results. Depending upon the nature of the data, the statistical tests were chosen. P value of < 0.05 was considered to be significant.

Independent sample t test was done to compare the means of Group 1 and Group 2.

The data analyzed by using ANOVA with unpaired T-test to compare the measurements of pain, swelling, Mouth opening, soft tissue healing and Hard tissue formation& between the two groups. The results were averaged (mean + standard deviation) for each parameter between the 2 groups.

In all the tests P value less than 0.05 was accepted as statistical significant.None of the patients reported adverse events. Total 30 patients in which 15 control and 15 study patients were enrolled in the study and randomly divided into two groups. The mean age of the patients was 28.90.

Study Groups:

Group A: Impacted tooth without CGF placement.

Group B: Impacted tooth with CGF placement.

Observations from table1:

Comparison of two groups with respect to PAIN at preoperative,1st and 7th postoperative days.

	MEAN ± STD DEVIATION		MEAN DIFFERENCE	95% CONFIDENCE INTERVAL OF THE DIFFERENCE		P VALUE
	GROUP 1	GROUP 2		Lower	Upper	
PRE OPERATIVE	7.80±.862	7.93±.799	-.133	-.755	.488	.664
IMMEDIATE POST OPERATIVE	5.00±.845	1.27±.594	3.733	3.187	4.280	<.001*
AFTER 1 WEEK	2.20±.862	.07±.258	2.133	1.657	2.609	<.001*

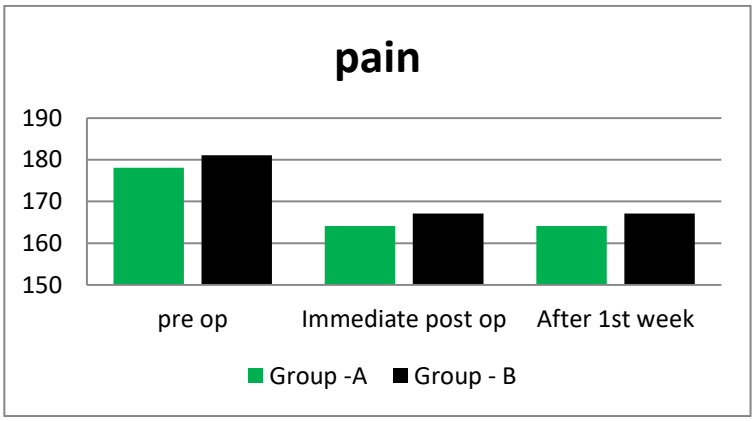
***Independent paired t test p value<0.05 = statistically significant.**

On **Preoperative day** the mean pain scores were 7.80 in group I and 7.93 in group II.

On **1st postoperative day** the mean pain scores observed were 5.00in group I, 1.27 in group 2. Though the mean pain score was comparatively less in group II but it was statistically significant at 5% level of significance, P value was .001*.

On after 1 week the mean swelling scores were 2.20 in group I,.07 in group II. Though the mean pain score was comparatively less in group II but it was statistically significant at 5% level of significance, P value was less than .001*.

Statistical significant difference was observed between two groups with respect to swelling scores at preoperative, 1st, and 7th postoperative days at 5% level of significance ($p<0.05$)



Observations from table 2:

Comparison of three groups with respect to EDEMA (or) SWELLING at preoperative, 1st and 7th post-operative days.

	MEAN ± STD DEVIATION		MEAN DIFFERENCE	95% CONFIDENCE INTERVAL OF THE DIFFERENCE		P VALUE
	GROUP 1	GROUP 2		Lower	Upper	
PRE OPERATIVE	12.87±.743	12.60±.737	.267	-.287	.820	.332
IMMEDIATE POST OPERATIVE	13.93±1.033	8.87±1.125	5.067	4.259	5.875	<.001*
AFTER 1 WEEK	12.87±.743	.00±.000	12.867	12.474	13.260	<.001*

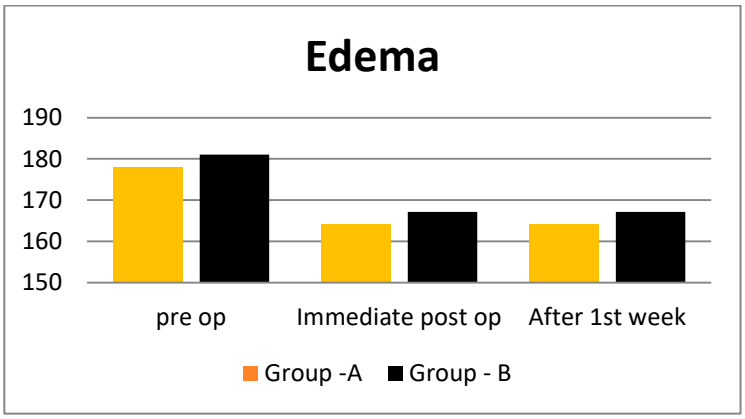
***Independent paired t test p value<0.05 = statistically significant**

On **Pre-operative** day the mean swelling scores were 12.87 in group I, 12.60 in group II.

On **1st post-operative** day the mean swelling scores observed were 13.93 in group I, 8.87 in group 2. Though the mean swelling or edema score was comparatively less in group II but it was statistically significant at 5% level of significance, P value was <.001*.

On **7 th post-operative** day the mean swelling scores were 12.87 in group I and .00 in group II. Though the mean swelling score was comparatively less in group II but it was statistically significant at 5% level of significance, P value was <.001*

Statistically significant difference was observed between two groups with respect to swelling scores at pre-operative, 1st and 7th post-operative days at 5% level of significance ($p<0.05$).



Observations from table 3:

Comparison of two groups with respect to TRISMUS (or) MOUTH OPENING scores at preoperative, 1st and 7th post-operative days.

	MEAN ± STD DEVIATION		MEAN DIFFERENCE	95% CONFIDENCE INTERVAL OF THE DIFFERENCE		P VALUE
	GROUP 1	GROUP 2		Lower	Upper	
PRE OPERATIVE	45.67± 6.287	38.60± 7.689	7.067	1.814	12.319	.010*
IMMEDIATE POST OPERATIVE	25.07± 4.200	35.33± 3.599	-10.267	-13.192	-7.341	<.001*
AFTER 1 WEEK	28.20± 4.092	41.07± 4.758	-12.867	-16.186	-9.548	<.001*

***Independent paired t test p value<0.05 = statistically significant**

On **pre-operative** day the mean mouth opening scores were observed in 38.60 group I and 38.60 in group II.

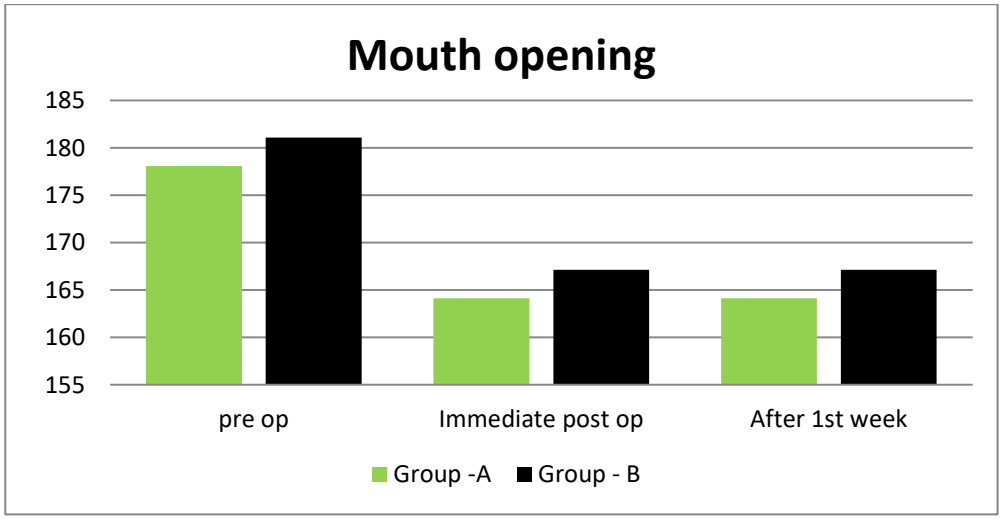
On **1st post-operative** day the mean mouth opening scores observed were 25.07 in group I and 35.33 in group II. The mean mouth opening score was comparatively more in group II which is statistically significant at 5% level of significance, P value was <. 0001

On **7th post-operative** day the mean mouth opening scores were 28.20 in group I and 41.07 in group II. The mean mouth opening score was comparatively more in group II which is statistically significant at 5% level of significance, P value was <. 001. (P<0.05)

In group II patients mouth opening is more in comparison with group I.

Statistically significant difference was observed between two groups on 1st and 7th post-operative days as the P value was <.001*. It means in group 2 patients mouth opening score is signicantly increased than group 1.

When comparing the two group's mouth opening was more in group II patients than group I mouth opening on 1st and 7th post-operative days.



Observations from table 4:

Comparison of three groups with respect to SOFT TISSUE HEALING at preoperative, 1st and 7th post-operative days.

	MEAN ± STD DEVIATION		MEAN DIFFERENCE	95% CONFIDENCE INTERVAL OF THE DIFFERENCE		P VALUE
	GROUP 1	GROUP 2		Lower	Upper	
PRE OPERATIVE	1.47±.516	1.33±.488	.133	-.242	.509	.473
IMMEDIATE POST OPERATIVE	1.67±.488	2.67±.617	-1.000	-1.416	-.584	<.001*
AFTER 1 WEEK	3.33±.488	4.60±.507	-1.267	-1.639	-.894	<.001*

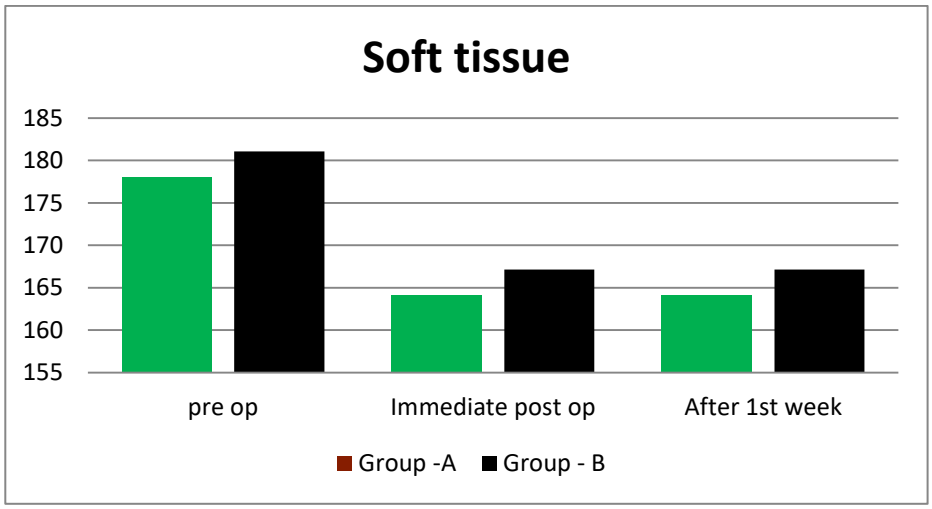
***Independent paired t test p value<0.05 = statistically significant**

On **Preoperative day** the mean swelling scores were 1.47 in group I, 1.33 in group II.

On **1st postoperative day** the mean swelling scores observed were 1.67 in group I and 2.67 in group 2. Though the mean soft tissue healing score was comparatively more in group II but it was statistically significant at 5% level of significance, P value was <.001*.

On **7th postoperative day** the mean swelling scores were 3.33 in group I and 4.60 in group II. Though the mean soft tissue score was comparatively more in group II but it was statistically significant at 5% level of significance, P value was <.001*

Statistically significant difference was observed between two groups with respect to soft tissue scores at pre-operative, 1st and 7th post-operative days at 5% level of significance (p<0.05).



Observations from table 5:

Table5: Comparison of two groups with respect to Hard tissue healing at preoperative, 1st, 7th day, 1st and 3rd month postoperative period

HARD TISSUE HEALING

	MEAN ± STD DEVIATION		MEAN DIFFERENCE	95% CONFIDENCE INTERVAL OF THE DIFFERENCE		P VALUE
	GROUP 1	GROUP 2		Lower	Upper	
PRE OPERATIVE	178.07±15.285	181.07±13.946	-3.000	-13.944	7.944	.579
IMMEDIATE POST OPERATIVE	164.13±13.809	167.13±11.594	-3.000	-12.536	6.536	.525
AFTER 1 WEEK	164.13±13.809	167.13±11.594	-3.000	-12.536	6.536	.525
1ST MONTH	179.00±15.264	186.60±15.445	-7.600	-19.085	3.885	.186
3RD MONTH	183.27±14.801	225.40±14.836	-42.133	-53.217	-31.049	<.001*

***Independent paired t test p value<0.05 = statistically significant**

On **Preoperative day** the mean swelling scores were 178.07 in group I and 181.07 in group II.

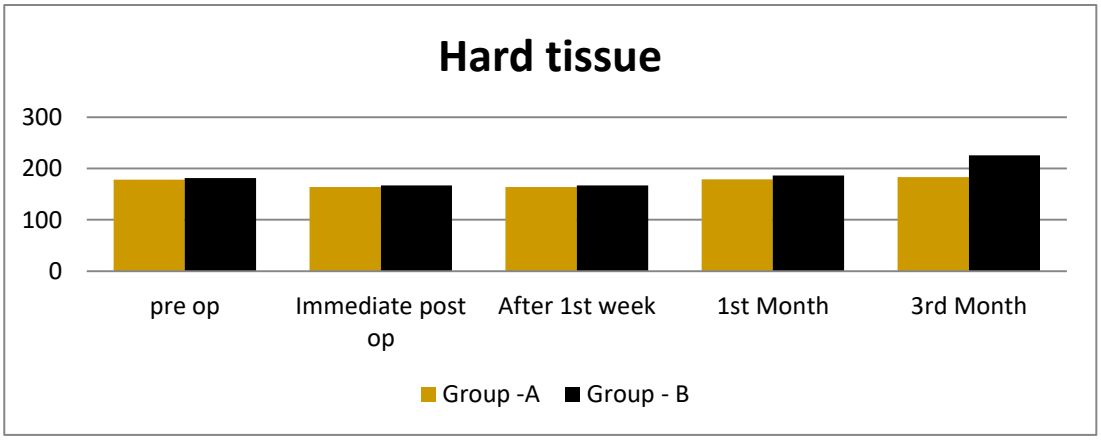
On **1st postoperative day** the mean swelling scores observed were 164.13 in group I and 167.13 in group 2. Though the mean soft tissue healing score was comparatively more in group II but it was statistically significant at 5% level of significance, P value was .579.

On **7th postoperative day** the mean swelling scores were 164.13 in group I and 164.13 in group II. Though the mean soft tissue score was comparatively more in group II but it was statistically significant at 5% level of significance, P value was .525

On **1st month** the mean swelling scores observed were 179.00 in group I and 186.60 in group 2. Though the mean soft tissue healing score was comparatively more in group II but it was statistically significant at 5% level of significance, P value was.525

On **7th month** the mean swelling scores were 183.27 in group I and 225.40 in group II. Though the mean soft tissue score was comparatively more in group II but it was statistically significant at 5% level of significance, P value was <.001*

Statistically significant difference was observed between two groups with respect to hard tissue healing scores at pre-operative, 1st and 7th post-operative days at 5% level of significance ($p<0.05$).


Hard tissue
300
200
100
0
pre op
Immediate post op
After 1st week
1st Month
3rd Month
Group -A
Group - B

DISCUSSION

Surgical removal of impacted mandibular third molars is the most frequent surgical procedure performed by Oral & Maxillofacial surgeons. The surgery involves elevation of a soft tissue flap, followed by adequate bone guttering and odontectomy.[27] These procedures cause a significant amount of tissue injury, leading to the release of various vasoactive chemical mediators, which initiate the process of inflammation and repair.

Thus, despite the diversified demands of practice, dental surgeons still face the problem of the removal of impacted mandibular third molars [28]. Both the patient and dentist must therefore have scientific evidence-based information concerning the estimated degree of surgical difficulty in each case [29].

MacGregor [30] made the first attempt to establish a model for assessing surgical difficulty. The classic Pell and Gregory classification has recently been found to be inadequate for the determination of surgical difficulty [31].

There are a number of previous studies carried out to evaluate surgical difficulty in the extraction of impacted mandibular third molars (28,31,32,33,34,35,36,). However, most of these studies are only based on dental factors determined through radiologic assessments (31,32,34,35,36,). While opinions may vary, most authors agree that these radiologic factors play some role in estimating difficulty

(32,33,34,35,31). Other authors believe it is difficult to estimate difficulty through radiologic methods alone and that actual difficulty can only be estimated intraoperatively (37). Some authors also believe that clinical variables, such as patient age, gender and weight, are also very important (33,34). Few authors have proposed indexes for measuring surgical difficulty (35,36). Pederson proposed such an index (28), but it is seldom used due to reports that it does not match actual surgical difficulty (35,39).

Surgical removal of impacted mandibular third molar causes significant pain, swelling and trismus even when done a traumatically.[40], [41] and is quite annoying to the patient and affects their quality of life by delaying the period of recovery. These complications are attributed to the inflammation produced as a result of surgical trauma.

From 1990's, till today growth factors have emerged as the "Holy Grail" in wound healing.[15] Researches by Dong-seok sohn and others showed that concentrated growth factors (CGF) improve bone formation and plays a vital role in osseointegration of implants. Growth factors play a major role to repair or generate tissues. Most of the growth factors are in blood plasma and platelets. So platelet concentrates contains sufficient growth factors such as platelet derived growth factors (PDGF), Transforming growth factors (TGF- β), Insulin like growth factors (IGF- I), Epidermal growth factors (EGF), Vascular

Endothelial Growth Factors (VEGF), basic Fibroblast Growth Factors (bFGF).[25]

Concentrated growth factors is known to have higher tensile strength, higher concentration of growth factors and higher resistance to flow than Platelet rich fibrin (PRF), Platelet rich plasma (PRP), and hence compressed CGF can be used as barrier membrane with growth factors as alternative collagen membrane. This barrier membrane induces faster formation and fast tissue healing.[25]

CGF & ITS IMPORTANCE

Concentrated growth factors CGF (Fig-15 (A) is well known to accelerate new bone formation. Other blood derivatives like Platelet rich Plasma uses complex protocols to prepare and chemical additives. Concentrated growth factor, overcomes these disadvantages. CGF does not require any chemical or allergenic additives such as Bovine thrombin or anticoagulants, so is free from viral transmission diseases. CGF is 100 % autologous fibrin.[24] CGF can be used alone or with a bone graft.[42] CGF with fibrin rich blocks induce fast new bone formation.[43]

Fabrication of CGF:

The calibrated centrifugation carried out with the Medifuge phase separator (Silfradent, Italy). The apparatus accurately designed so as to guarantee the maximum exploitation of the blood's potential by controlling the following, Speed, Time, Temperature, acceleration and controlled speed and Gravitational acceleration of approximately

RCF200. The development and growth of the fibrin gel block during the centrifugation and specially during the polymerisation, allows for a volume growth of the chains in all directions.[26] CGF, like PRF, does not require the inclusion of bovine thrombin or any anticoagulants. Additionally, altered protocols in receiving the blood sample and in the centrifuging procedure compare with PRF. Unlike PRF however, CGF uses variable rpm from 2400-2700 to separate cells in the venous blood, which results in fibrin rich blocks that are larger, denser and more affluent in growth factors than common PRF. This shows enhanced regenerative capacity and superior versatility when using the fibrin rich block.[26]

The CGF is characterised by four phases:

1. A superior phase represented by the serum (blood plasma in absence of fibrinogen and coagulation factors).
2. An interim phase represented by a very huge and dense polymerised fibrin block.
3. A liquid phase containing the Growth Factors, white line cells and stem cells waiting for stimulation and to differentiate into specialized cell types.
4. A lower red portion consists of a viscous, dense, platelet-rich coagulation.[26]

The phases and their components are:

1. Serum

Serum is the lightest and most liquid part of blood. It is fibrinogen-free and has only a few cells. It should be kept cool and mixed quickly to avoid denaturing the proteins.[26]

It is a clear and straw yellow in colour and consists of:

- 92% Water
- 7% proteins, mineral salts, Carbondioxide
- Proteins: albumin and antibodies
- Nutrients: glucides, amino acids, lipids and Enzymes
- Hormones
- Inorganic electrolytes

2. Fibrin Buffy Coat

The polymerized fibrinogen molecules (FG), the resultant fibrin block comprises three-dimensional polymer networks with interwoven fibres, all collected in a single phase in the form of a gel in a single phase. During polymerisation, the fibres grow in diameter.[26]

3. The Growth Factors and the unipotent Stem Cells:

Below the buffy coat and above the dense clot portion lies the growth factors and unipotent stem cells. This phase can be aspirated with a pipette and mixed with autologous bone to obtain an extremely high performance activated graft.[26]

4. Coagulum:

In the CGF technique, the red phase consists of concentrated red and white blood cells, platelets and clotting factors. It appears like a dark reddish dense gel, and can be used in its pure form or added with fibrin particles and/or autologous or heterologous bone when filling very enormous defective areas.[26]

CGF in regenerative surgery should therefore be considered as a multifactorial stimulation system. This versatility and multiplicity of applications makes it successful from all the other techniques proposed so far. [26]

Mode of action of CGF:

The ensuing fibrin clot or block is of a greater quality due to the concentration of factor XIII, fibrinogen and thrombin that is obtained. Factor XIIIa, which is activated by thrombin, cross links the fibrin clot to increase stability, strength and protection against plasmin mediated degradation. Clinically, this results in a clot with higher tensile strength, adhesive strength, and decline in haemostatic time (105 secs vs 360 secs).[26]

Besides the tensile fibrin membrane, a red phase of concentrated red blood cells and platelets are obtained. This is often mixed with either autogenous or other fillers for a more easy to handle and voluminous cavity filling method. In actual fact the CGF is an upgraded version of PRF with a strengthened fibrin matrix and boosted growth

factors and cytokines.[26] During normal wound healing, the fibrin matrix is essential in arrest of bleeding, however more crucial is its role in acting as the initial scaffold for the new extracellular matrix. It allows mixing of cells and healing proteins to the scaffold, such as platelets, White blood corpuscles, fibroblasts and osteoblasts, endothelial cells, and smooth muscle cells.[26]

Keratinocytes bind to fibrin. By expressing sites for binding of cytokine, growth factors and adhesion molecules for cells, wound healing was indirectly promoted by fibrins. Fibrin has also been shown in animal models to be an important determinant of angiogenesis, as fibrin deposited in subcutaneous tissue initiates angiogenesis.[26]

In addition, studies have shown that wound healing is largely dictated by fibrin structure; in density, porosity, number of branch points and permeability. The fibrin physical structures are determined by many factors including clotting rate, Factor XIII concentration, chloride ions, pH, and thrombin etc. Optimizing these conditions is part of the aim of the CGF protocol.[26]

Pathological alterations of these fibrin fibers occur in diseases like diabetes and this clearly leads to disturbances in wound healing process. Thus these are the patients that are most likely to benefit from CGF.[26]

Further to the fact that CGF not only uses an autogenous source of growth factors and membrane, there are no added derived products of

animals as in PRP. With no anticoagulants added, the platelets begin to be activated naturally alongside the coagulation cascade. The resulting matrix or membrane rich in fibrin works synergistically with these growth factors. [26]

The present study is in accordance with the very similar studies conducted by Renu Kundu et al., with Platelet rich plasma (PRP) on bone and implant stability revealed marked improvement in implant stability. But the distinction is that, with CGF, the level of enhancement acquired is phenomenon and starts at the early stages of bone healing and osseointegration. Also the bone density is enhanced above the baseline level, which could mean that bone mineralization is also enhanced by CGF. A more focussed study on that subject may shine light in this area.

CONCLUSION

The results of this study indicates that CGF is significantly better in regeneration of bone around the surgical removal of mandibular molar when comparing with non-CGF groups. Although, CGF showed improvement in both soft tissue healing and bone formation, there is much differences in bone level changes on mesial and distal side of the surgical removal of impacted teeth between two groups. Though, the present study was done with a sixth month follow-up and the osseous regeneration was only measured indirectly over computer aided software (Digora), CGF did attribute to be a much simpler and a better platelet concentrate, in promoting osseous regeneration. CGF also aided in increasing the density of bone around the surgical removal of impacted 3^{rd} molar teeth from baseline to a much higher level. This attribute could be used in cases where bone mineralization is compromised. But the exact action of CGF on bone mineralization needs to be studied further.

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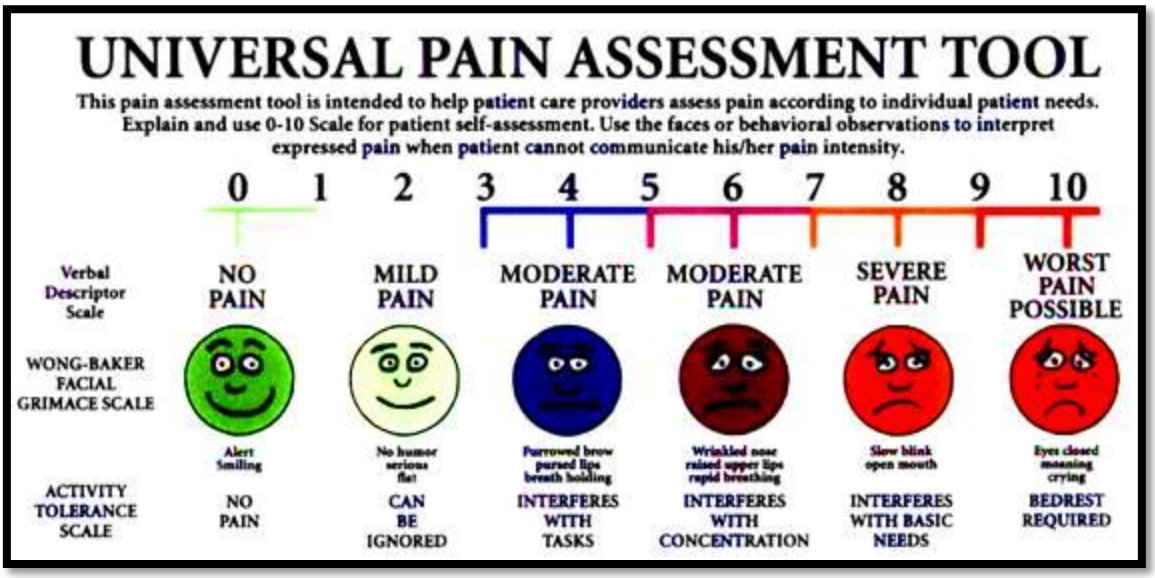
PICTURES:

Figure 1: Pain (Visual analogue scale)



MEASUREMENT OF FACIAL SWELLING

Figure 2: Tragus to corner of mouth measurement

Figure 3: Tragus to pogonion measurement

Figure 4: Lateral corner of the eye to angle of mandible

EVALUATION OF TRISMUS

Figure 5: Measurement of Interincisal distance

Figure 6: Armamentarium

Control group pictures

Figure 7: Intra oral peri apical radiograph

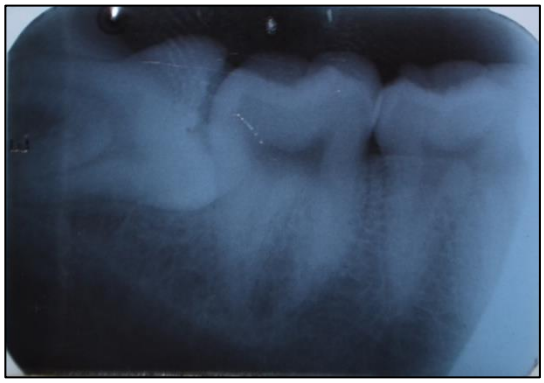


Figure 8: Pre-operative

Figure 9: Incision

Figure10: Extracted mandibular third molar

Figure11: Wound closure

Experiment group pictures

Figure 12: Pre-operative

Figure 13: Pre- OPG

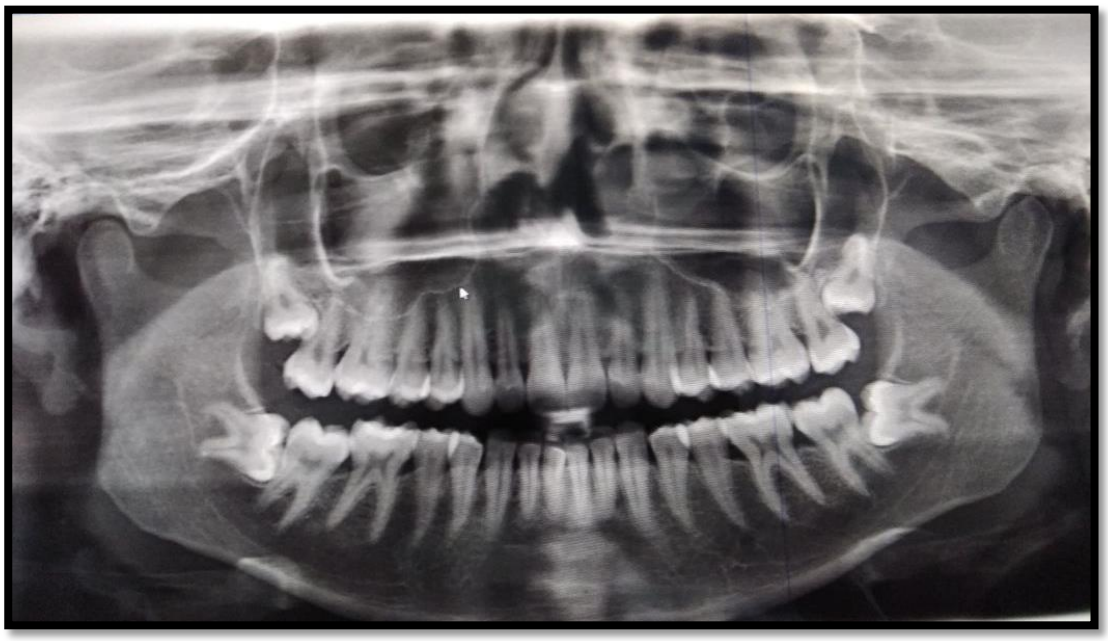


Figure 14: Tooth exposed

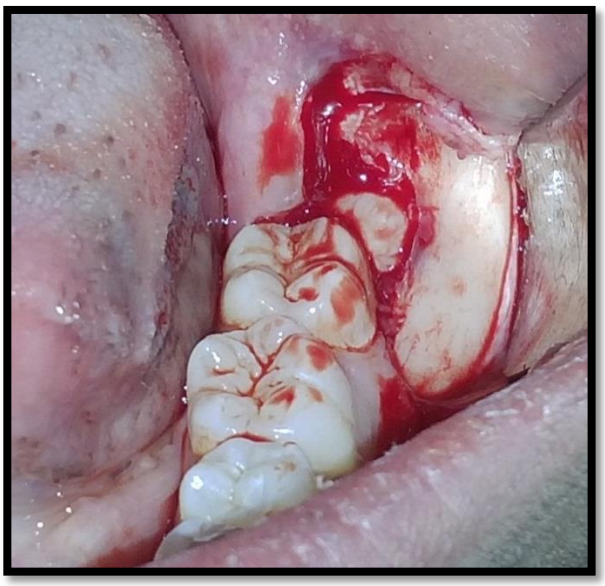


Figure 15: CGF PLACEMENT

15 (A)

15(B)

15(C)

Figure 16: CLOSURE

Figure 17: POST OPG

Adhiparasakthi Dental College & Hospital

Department Of Oral & Maxillofacial Surgery

Impaction Case Sheet

NAME		**DATE**	
OP NO		**AGE**	
ADDRESS		**SEX**	
		DATE OF BIRTH	
		OCCUPATION	

CHIEF COMPLAINT

HISTORY OF PRESENTING ILLNESS

PAIN		**SWELLING**	
PAIN	SWELLING	Site	
Location		Site	
Character		Size	
Severity		Shape	
Duration		Colour	
Aggravating Factors		Edge	
Relieving Factors		Number	
Spontaneity		Pulsation	
Diurnal Variation		Peristalsis	
		Repiration	
Postural Variation		Coughing	
		Deglutition	
		Skin Over the Swelling	

PAST MEDICAL HISTORY

PAST SURGICAL HISTORY

PAST DENTAL HISTORY

PERSONAL HISTORY

FAMILY HISTORY

GENERAL EXAMINATION	
Temperature	
Blood Pressure	
Pulse	
Respiratory Rate	
Gait	
Orientation	
Build	
Nourishment	
Pallor	
Cyanosis	
Icterus	
Clubbing	
Pedal Edema	
General Lymphadenopathy	
Others	

EXTRA ORAL EXAMINATION	
Extra Oral Swelling	Yes ☐ No ☐
If Yes – Describe	
INSPECTION	
SITE	
SIZE	
SHAPE	
COLOUR	
EDGE	

NUMBER	
PULSATION	
PERISTALSIS	
REPIRATION	
COUGHING	
DEGLUTITION	
SKIN OVER THE SWELLING	
PALPATION	
INSECTORY FINDINGS	
TEMPERATURE	
TENDERNEESS	
SIZE	
SHAPE	
EXTENT	
SURFACE	
EDGE	
FLUCTUATION	
TRANSLUCENCY	
IMPULSE ON COUGHING	
REDUCIBILITY	
COMPRESSIBILITY	
PULSALITY	
FIXATION	
RELATIONS	
PERCUSSION	
FINDINGS	
AUSCULTATION	
FINDINGS	

TMJ Examination	☐ Tenderness ☐ Clicking ☐ Crepitus ☐ Deviation ☐ Any Other Abnormality		
Specify Other Abnormalities			
Rima Oris	☐ Macrostomia ☐ Normal ☐ Microstomia		
INTRA ORAL EXAMINATION			
Teeth Present			
Tongue : ☐ Macroglossia ☐ Normal ☐ Microglossia (Specify If Any Other Abnormality Detected)			
Mouth Opening		Trismus	Present / Absent
Eruption Status	☐ Erupted ☐ Partially Erupted ☐ Non Erupted		
Tooth		Type Of Impaction	☐ Soft Tissue ☐ Bony
Third Molar Periodontal Status			
Second Molar Periodontal Status			
Third Molar Caries & Vitality			
Second Molar Caries & Vitality			
Third Molar Restorative Status			
Pericoronitis	Yes ☐ No ☐		
Position & Thickness Of External Oblique Ridge			
Reason For Extraction	☐ Pericoronitis		
	☐ Periodontitis		
	☐ Associated Cyst / Tumor		
	☐ Caries		
	☐ Prosthetic Reason		
	☐ Orthodontic Reasons		
	☐ Involvement In Fracture Line		
	☐ Prior To Orthognathic Surgery		
Others			

INVESTIGATIONS	
Routine Blood Investigations	☐ Bleeding Time
	☐ Clotting Time
	☐ Random Blood Glucose
	☐ Hemoglobin
	☐ HIV
	☐ HbsAg
	☐ HCV
	☐ Others
	Specify :
Radiographs	☐ Intra Oral Periapical Radiograph
	☐ Ortho Pan Tomography
	☐ CT
	☐ CBCT
	☐ Others
	Specify :

INTERPRETATION OF RADIOGRAPHS	
Bone Sclerosis	☐ Yes ☐ No
Tooth Lock	☐ Yes ☐ No
Shape Of Crown	
Root Formation	☐ Completed ☐ Not Completed
Number Of Roots	
Ankylosis	☐ Yes ☐ No
Hypercementosis	☐ Yes ☐ No
Width Of The PDL Space	☐ Less ☐ Normal ☐ Increased
Distal Bone Loss	☐ Yes ☐ No
Root Pattern	☐ Loss & Slender ☐ Short & Stout
Divergence Of Roots	☐ Yes ☐ No
Bulbosity Of Roots	☐ Yes ☐ No
Dilaceration	☐ Yes ☐ No
Follicular Space	☐ Present ☐ Absent
Others	

WINTER'S WAR LINES (1926)	
White Line	
Amber Line	
Red Line	
Others	

MODIFIED PEDERSON'S SCORING (1988)		
Spatial Relationship	Relation With Ramus	Relative Depth
Mesioangular – 1	Class I – 1	Position A - 1
Vertical – 2	Class II – 2	Position B - 2
Horizontal – 3	Class III - 3	Position C - 3
Distoangular – 4		
Difficulty Score :		Slightly Difficult : 3 - 4 Moderately Difficult : 5 - 6 Very Difficult : 7 - 10
Others		

SCORING DETAILS FOR WHARFE'S ASSESSMENT		
Winter's classification	Horizontal	2
	Distoangular	2
	Mesioangular	1
	Vertical	0
Height of the mandible	1 - 30 mm	0
	31 – 34 mm	1
	35 – 39 mm	2
Angulation of second molar	1 – 59 °	0
	60 – 69 °	1
	70 – 79 °	2
	80 – 89 °	3
	>90 °	4
Root shape	Complex	1
	Favourable curvature	2
	Unfavourable curvature	3
Follicle Size	Normal	0
	Possible enlarged	1
	Enlarged	2
Path of exit	Space available	0
	Distal cusps covered	1
	Mesial cusps covered	2
	Both covered	3
TOTAL SCORE		
OTHERS		

PELL & GREGORY'S CLASSIFICATION (1933)
A. Relation Of The Tooth To The Ramus Of The Mandible & 2nd Molar
☐ Class I
☐ Class II
☐ Class III
B. Relative Depth Of The Third Molar In Bone
☐ Position A
☐ Position B
☐ Position C
C. The Position Of The Long Axis Of The Impacted Mandibular Third In Relation To The Long Axis Of The Second Molar (Winter's Classification)
☐ Vertical
☐ Horizontal
☐ Inverted
☐ Mesioangular
☐ Distoangular
☐ Buccoangular
☐ Linguoangular
Any Of These May Also Occur In
☐ Buccal Version
☐ Lingual Version
☐ Torsi Version
Others

RELATIONSHIP TO THE INFERIOR ALVEOLAR CANAL (HOWE & PONTON 1960 ROOD'S & SHEHAB 1990)
A. Related But Not Involving The Canal
☐ Separated
☐ Adjacent
☐ Superimposed
B. Related To Changes In The Canal
☐ Darkening Of The Root
☐ Dark & Bifid Root
☐ Narrowing Of The Root
☐ Deflected Root
C. Related With Changes In The Canal
☐ Interruption Of Lines
☐ Converging Canal
☐ Diverted Canals

PROCEDURE	
Type Of Anesthesia	☐ LA ☐ LA + Sedation ☐ GA
Sedation (If Used)	☐ Oral ☐ Inhalational ☐ IV
LA Administered	
Incision & Flap	☐ Terence Ward
	☐ Modified Ward
	☐ Envelope
	☐ Other Types (Specify)
Bone Cutting Techniques	☐ Bur ☐ Chisel
Odontectomy	☐ Yes ☐ No
Delivery Of Tooth	☐ Forceps ☐ Elevator
Duration Of Surgery	

Operative Notes

OTHERS :

CLOSURE	
Styptics Used	☐ Abgel ☐ Bone Wax ☐ Others ☐ None
Sutures Used	☐ Absorbable ☐ Non Absorbable

PERIOPERATIVE ASSESSMENT	
Patient Co Operation	☐ Good ☐ Adequate ☐ Poor
Mouth Opening	☐ Satisfactory ☐ Not Satisfactory
Gag Reflex	☐ Yes ☐ No
Adequate Pain Control Achieved	☐ Yes ☐ No
Others	

MODIFIED PARANT SCALE (1997)	
Easy 1	Extraction Requiring Forceps Only
Easy 2	Extraction Requiring Osteotomy Only
Hard 3	Extractions Requiring Osteotomy & Coronal Section
Difficult 4	Complex Extractions (Requiring Root Resection)

POST OPERATIVE MEDICATION					
Antibiotic Used		Dose / Route		Duration	
Corticosteroids		Dose / Route		Duration	
Analgesics		Dose / Route		Duration	
Enzyme	☐ Yes ☐ No				

POST OPERATIVE REVIEW					
1ST Visit Date		1ST Visit Time		No Of Post Op Days	
Oedema	☐ Yes ☐ No				
Wound Healing Status					
Dehiscence Of Socket	☐ Yes ☐ No				
Trismus	☐ Yes ☐ No				
Dry Socket	☐ Yes ☐ No				
Parasthesia	☐ Yes ☐ No	☐ Lingual ☐ Mental ☐ Both			
Any Other Associated Symptom					
2nd Visit If Required					

JR	CONSULTANT	HOD

Adhiparasakthi Dental College & Hospital

Consent Form for the evaluation of early accelerated tissue healing in the surgically removed impacted mandibular 3rd molar socket using concentrated growth factors

Date:

Name of the patient:

Age / Sex:

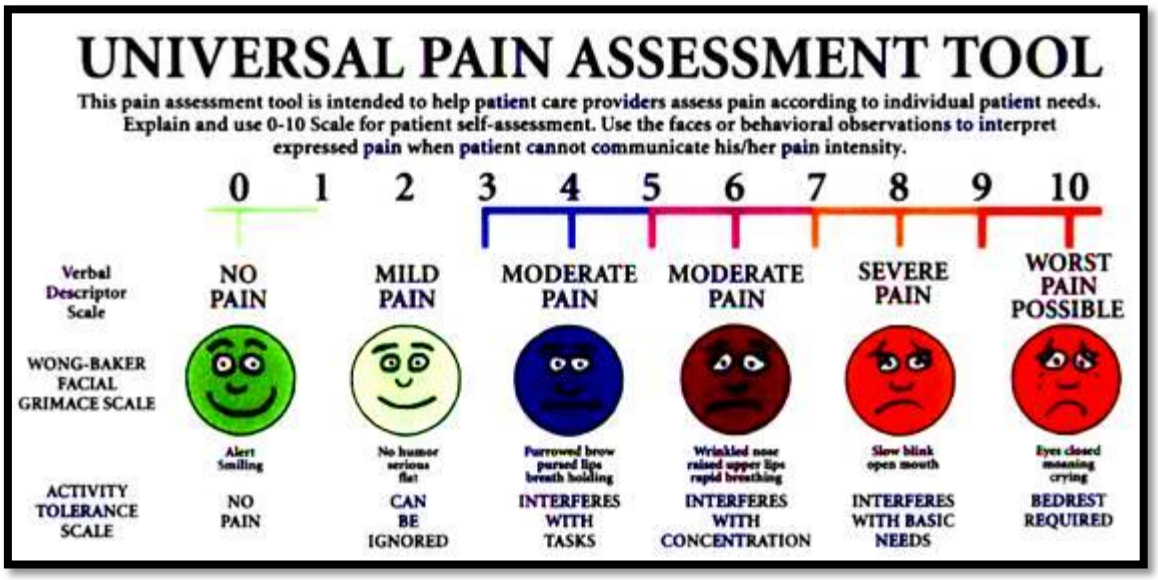
OP Number:

The evaluation procedure of the early accelerated tissue healing in the surgically removed impacted 3rd molar teeth socket has been explained to me and I have also had the opportunity to have my doubts answered satisfactorily. The operating procedures, alternatives, advantages and disadvantages have been discussed including the consequences of not having the surgical procedure. I also understand the results of my clinical examination, proposed treatment plan(s), possible complications and anticipated results. I voluntarily accept any or all possible risks that may be associated with any part of these procedures. I understand it is my duty to diligently follow the instructions given to me in regard to the procedure. I testify that I have read the consent form and give my consent form for the treatment.

Signature of the patient Signature of the doctor

EVALUATION CHART DETAILS

1. PAIN - VISUAL ANALOGUE SCALE



2. EDEMA (*Measuring with tape or 2-0 Nylon thread****)***

1.Distance between the corner of the mouth to ear lobule

2. Distance between the Ala of the nose to Angle of the mandible

3. WOUND DEHISCENCE

Discoloration over the mucosa, Discharge, Gaping

4.Mouth opening (Scale**)**

Distance between the Incisal edges of the upper and lower central incisors**.**

5. SOFT TISSUE HEALING (Landry et al Index**)**

A.VERY POOR:

Tissue colour : > 50% Gingival red

Response to palpation : Bleeding

Granulation tissue : Present

Incision margin : Not epithelialized, with loss of epithelium beyond incision

B. POOR:

Tissue colour: > 50% Gingival red

Response to palpation: Bleeding

Granulation tissue: Present

Incision margin: Not epithelialized, with CT exposed

C. GOOD:

Tissue colour : >25 and > 50% Gingival red

Response to palpation: Bleedings

Granulation tissue: Present

Incison margin: Not epithelialized, with CT exposed

D. VERY GOOD

Tissue colour : <25 of gingival red

Response to palpation: No Bleeding

Granulation tissue: None

Incision margin: No Connective tissue exposed

E. EXCELLENT

Tissue colour: All tissues pink

Response to palpation: No Bleeding

Granulation tissue: None

Incision margin: No connective tissue exposed

5. **BONE TISSUE HEALING**: Bone density

PRE and Post OP (IOPA or OPG)

ADHIPARASAKTHI DENTAL COLLEGE AND HOSPITAL

Melmaruvathur, Tamilnadu-603019

An ISO 9001:2008 certified institution.Accredited by NAAC with "B" grade.

Recognised by DCI, New Delhi. Affiliated to: The Tamil Nadu Dr. M.G.R. Medical University, Chennai.

This ethical committee has undergone the research protocol submitted by **Dr. R. MURALIDHARAN** Post Graduate Student, Department of prosthodontics under the title "**A Prospective Randomized Control Study to Compare The Effiacacy of Concentrated Growth Factor Following Surgical Removal of Impacted Mandibular 3rd Molar**", Reference No: **2015-MD-BrIII-GOK-06/APDCH** under the guidance of **DR T. RAMAKRISHNAN** for consideration of approval to proceed with the study.

This committee has discussed about the material being involved with the study, the qualification of the investigator, the present norms and recommendation from the Clinical Research scientific body and comes to a conclusion that this research protocol fulfils the specific requirements and the committee authorizes the proposal.

Date: **CHAIR PERSON**

- Inform IEC/IRB immediately in case of any issue(s) / adverse events.
- Inform IEC/IRB in case of any change of study procedure, site and investigator.
- Annual report to be submitted to IEC/IRB.
- Members of IEC/IRB have right to monitor the trial with prior intimation.